



THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

DoD Smallpox Vaccination Program Safety Summary, as of January 31, 2003

Background:

On December 13, 2002, the President directed smallpox vaccinations for about 500,000 selected military personnel. DoD vaccinations began immediately for emergency response personnel and hospital staff members. Comprehensive training programs in vaccination technique, infection-control safeguards, screening and education methods, adverse event monitoring, and product storage and handling, aggressively launched in October 2002, made immediate vaccinations possible. In early January 2003, DoD began smallpox vaccinations of selected US military forces, and emergency-essential civilians and contractors deployed or deploying in support of U.S. Central Command missions.

Program Status:

DoD healthcare workers vaccinated against smallpox	3,665
DoD operational forces vaccinated against smallpox	Not released publicly. multiple tens of thousands.

* NOTE: All appropriate program information is provided to federal health authorities, including all safety-surveillance data.

Safety Assessment:

DoD smallpox vaccine recipients have experienced the temporary symptoms expected after smallpox vaccination (e.g., itching, swollen lymph nodes, fever, malaise).

Sick leave, overall	3% of vaccinated people
Sick leave after primary (first) vaccination	4% to 5%
Sick leave after revaccination	1% to 2%
Average length of sick leave	1.5 days
Auto-inoculation (inadvertent infection)	0 cases
Transfer of vaccinia virus to contacts	0 cases
Treatments with vaccinia immune globulin (VIG)*	0 cases
Deaths due to smallpox vaccination	0 cases
Noteworthy cases	2, described below

* NOTE: VIG - an antibody product used to treat certain severe skin reactions after vaccination.

Noteworthy Adverse Events:

On January 26, a U.S. Army soldier was admitted for encephalitis in an overseas military hospital. The 23-year-old male had been vaccinated against smallpox prior to deployment. He became ill eight days after the vaccination and was medically evacuated to the facility where he is being treated. The possibility of a connection between the encephalitis and the vaccination is being investigated. Diagnostic studies did not establish vaccinia virus as a cause, but the timing of the encephalitis acts as circumstantial evidence. Information about the case was shared with civilian health authorities shortly after the situation was recognized. He has markedly improved, is in good condition, and is expected to be released from the hospital soon. For privacy reasons, his identity is not being released.

On January 25, a U.S. Army soldier at a U.S. base developed a rash about 10 days after smallpox vaccination that included several pustules (pus-filled blisters). The 30-year-old man's rash appears to qualify as "generalized vaccinia," one of the expected and somewhat rare skin reactions after smallpox vaccination. Generalized vaccinia can sometimes develop into a serious skin condition. But in this case, the soldier is well and continues to work at his usual location. Information about the case was shared with civilian health authorities. For privacy reasons, his identity is not being released.

Perspective:

"Our safety experience with smallpox vaccinations to date is consistent with what we expected overall. We have seen a small number of adverse reactions to the vaccine, mostly minor. There have been two significant reactions. We can expect additional reactions to occur; some will be significant reactions. For our two service members who experienced significant reactions, we provided prompt, excellent care and both are now doing well."

- *William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs*